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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,306

06/20/2005

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,306	<b>Applicant(s)</b> O'ROURKE ET AL.	
	<b>Examiner</b> ANN SCHILLINGER	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 7-10, 14, 17, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Iyer et al. (US Pat. No. 6,726,923). Iyer et al. discloses the following of claim 1: a method of treating a stiffened blood vessel, said method comprising at least substantially encasing a stiffened portion of said blood vessel (col. 5, lines 22-54 indicates that the prior art may to blood vessels that have been stiffened due to calcification; and col. 13, lines 14-20) with an elastic membrane formed of biocompatible material (col. 10, lines 11-20), such that said membrane engages said stiffened portion of said blood vessel to thereby reduce the external diameter of said stiffened portion of said blood vessel, passively carry at least a portion of blood pressure loads acting on said blood vessel throughout systole and diastole and reduce the effective stiffness of said stiffened portion of said blood vessel, said elastic membrane having a stiffness less than the stiffness of said stiffened portion of said blood vessel (col. 11, lines 21-56 show that the PTFE's physical support structure will act to passively carry at least a portion of the blood pressure loads that pass through the encased blood vessel).

Iyer et al. discloses claim 2 in col. 5, lines 10-21.

Iyer et al. discloses claim 5 in col. 7, lines 7-20.

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Iyer et al. discloses the following of claim 7: the method of claim 1 wherein said stiffened portion of said blood vessel is in a stiffened (col. 5, lines 22-54) and dilatated (due to the inflammation of col. 6, lines 56-67) state prior to treatment.

Iyer et al. discloses the following of claim 8: the method of claim 1 wherein said membrane is in the form of a sheet (2), said stiffened portion of said blood vessel being encased by wrapping said membrane sheet around the circumferential periphery of said stiffened portion of said blood vessel (Figs. 6-9) and securing opposing end portions of said membrane (via elements 6 and 9).

Iyer et al. discloses claims 9 and 10 as shown in Figures 6-9.

Iyer et al. discloses the following of claim 14: the method of claim 8 wherein the opposing end portions of said membrane are secured by way of interlocking structures (6, 9) formed on, or fixed to, each of said opposing end portions.

Iyer et al. discloses the following of claim 17: the method of claim 1 wherein said membrane is in the form of a spiral (16), said stiffened portion of said blood vessel being encased by spirally wrapping said membrane spiral around the circumferential periphery of said stiffened portion of said blood vessel (Fig. 4A-4B).

Iyer et al. discloses the following of claim 28: a method of treating a blood vessel, said blood vessel having a native tissue portion and a synthetic portion grafted in line with said native tissue portion (col. 7, lines 7-20), said synthetic portion having a greater stiffness than the stiffness of said native tissue portion (col. 5, lines 22-54), said method comprising at least substantially encasing said synthetic portion with an elastic membrane formed of biocompatible material (col. 10, lines 85 through col. 11, lines 20; col. 13, lines 14-20) such that said membrane

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engages said synthetic portion to thereby reduce the external diameter of said synthetic portion, passively carry at least a portion of blood pressure loads acting on said blood vessel throughout systole and diastole and reduce the effective stiffness of said synthetic portion of said blood vessel, said elastic membrane having a stiffness less than the stiffness of said synthetic portion of said blood vessel (col. 11, lines 21-56).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Khanghani et al. (US Pat. No. 6,984,201). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach placing the device on an artery such as the ascending aorta. Khanghani et al. teaches a blood circulation device on the ascending aorta in col. 9, lines 8-29 for the purpose of properly maintaining the heart's bloodflow. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Iyer et al. on the ascending aorta in order to properly maintain the heart's bloodflow.

Claims 6 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Chuter (US Pat. No. 5,387,235). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach constructing the device from a graft of woven polyester. Chuter teaches a stent with a woven polyester graft in col. 9, lines 12-43 for the

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purpose of utilizing the material's elasticity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by constructing it from a graft of woven polyester in order to utilize the material's elasticity.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Barefoot et al. (US Pat. No.3,726,279). Regarding claims 11, 12, and 14, Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach using sutures or a clamp on the ends of the prosthesis. Barefoot teaches a vascular cuff with sutures (27) and a clamp (30; Fig. 9) for the purpose of securing the prosthesis in its desired shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by using sutures or clamps on the ends of the prosthesis in order to secure the prosthesis in its desired shape.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Spaulding (US Pat. No. 5,304,200). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach welding the ends of the prosthesis. Spaulding teaches a stent with welded ends in col. 5, lines 13-49 for the purpose of securing the prosthesis in its desired shape. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by welding the ends of the prosthesis in order to secure the prosthesis in its desired shape.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Jones (US Pat. No. 4,202,349). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach markings on the prosthesis. Jones teaches a stent with markings in col. 2, line 52 through col. 3, line 16 for the purpose of helping the physician to

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properly locate the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by placing markings on the prosthesis in order to help the physician to properly locate the prosthesis.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Dusbabek et al. (US Pub. No. 2001/0007082). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach how the sheet membrane is formed. Dusbabek et al. teaches a stent where a cylinder is cut to form different structures to be used with the prosthesis in paragraphs 0074-0076 for the purpose of allowing the user to create the desired shape for the prosthesis. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by using a cut cylinder to form different structures to be used with the prosthesis in order to allow the user to create the desired shape for the prosthesis.

Claims 18-24 are rejected under 35 U.S.C. 103(a) as being anticipated by Iyer et al. The reference is silent as to the properties of size and stiffness, as claimed by the Applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthesis with the claimed physical characteristics, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Silverstrini et al. (US Pat. No. 4,834,755). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach using elastic polyurethane in the prosthesis. Silverstrini et al. teaches a biological prosthesis using elastic polyurethane in

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columns 5 and 6 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by using elastic polyurethane in the prosthesis in order to utilize the material's biocompatibility.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Silverstrini et al. (US Pat. No. 4,834,755). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach using elastic polyurethane in the prosthesis. Silverstrini et al. teaches a biological prosthesis using elastic polyurethane in columns 5 and 6 for the purpose of utilizing the material's biocompatibility. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by using elastic polyurethane in the prosthesis in order to utilize the material's biocompatibility.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of Wellman et al. (US Pub. No. 2003/0065303). Iyer et al. teaches the invention substantially as claimed, however, Iyer et al. does not teach implanting the device thoracoscopically. Wellman et al. teaches a biological prosthesis whose implantation is done thoracoscopically in paragraph 0016 for the purpose of allowing the user to accurately place the device on the damaged blood vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Iyer et al. by implanting the device thoracoscopically in order to allow the user to accurately place the device on the damaged blood vessel.



***Response to Arguments***

Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./  
Examiner, Art Unit 3774

/DAVID ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774

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